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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/449,077    11/24/99    HUNIG

D    12254/

EXAMINER

HM22/0315

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ART UNIT

PAPER NUMBER

1644  
DATE MAILED:

03/15/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/449,077	Applicant(s) HUNIG, DR. THOMAS	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 1999.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____        |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)       |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input checked="" type="checkbox"/> Other: <u>Copy of Decision on Petition</u> |

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#### DETAILED ACTION

1. Applicant is reminded to submit a new declaration as per the "Conclusion" of the Decision of Petition (Paper No. 8, filed 9/27/00), claiming benefit under 35 USC 120 to PCT/DE98/01499 and under 35 USC 119 for the prior German application. A copy of the Decision on Petition is attached for Applicant's convenience.

Based upon the Decision denying 371 status, regular US restriction practice applies to the following restriction requirement.

#### *Restriction Requirement*

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. For examination purposes:

"Use" claims are prosecuted as "methods of use" based upon the *first recited* use. Additional uses recited within the "Use" claim are considered intended uses and carry no patentable weight *per se*.

Applicant is reminded that such "Use" claims are improper process claims and are subject to rejection under both 35 USC 101 and 35 USC 112, first paragraph.

In the claims drawn to a procedure for the production of monoclonal antibodies, Applicant has presented two patentably distinct methods: a method for the production of monoclonal antibodies using hybridoma cells and a method for the production of monoclonal antibodies that are humanized. These methods are distinct because they involve different method steps in the production of different products. In addition, both the humanized and non-humanized monoclonal antibodies can be produced by alternate methods, such as antibody phage display. Therefore the restriction has been set forth for each method as a separate group, irrespective of the format of the claims.

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4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 13-15 and 24, drawn to anti-CD28 monoclonal antibodies and hybridomas producing the antibody, classified in Class 530, subclass 388.1; and Class 435, subclass 346.

II. Claims 5-6, 16-17, 25 and 29-31, drawn to a method for the production of a monoclonal antibody using hybridoma cells, classified in Class 435, subclass 70.21.

III. Claims 5, 16-17 and 25, drawn to a method for the production of a monoclonal antibody *that is humanized*, classified in Class 435, subclass 70.21 and Class 530, subclass 387.3.

IV. Claims 7-10, 18-19, 26 and 32-40, drawn to a method for the production of a medicine comprising an anti-CD28 monoclonal antibody, classified in Class 424, subclass 130.1.

V. Claims 11-12, 20-23 and 27-28, drawn to a method or procedure for treating a disease with an anti-CD28 monoclonal antibody, classified in Class 424, subclass 144.1.

5. Groups II - V are different methods. Each method differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups II/III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the antibody can be produced using phage display technology or viral transformation of the antibody-producing cell.

7. Groups I and IV/V are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used for affinity purification, in addition to the methods recited.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 14, 2001

PHILLIP GAMBEL  
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PRIMARY EXAMINER  
TECH CENTER 1600  
3/15/01